



AUTOMATIC LIQUID PACKAGING, INC.

July 20, 1999

2200 LAKE SHORE DRIVE WOODSTOCK, ILLINOIS 60098-7498 USA
TELEPHONE 815 338 9500 FACSIMILE 815 338 5504
<http://www.alp-bfs.com>

Food and Drug Administration
5630 Fishers Lane Room 1061
Rockville, MD 20852

RE: Application for Exemption from 21 CFR 201.66 (OTC Labeling Format)
Regular Eye Drops

To Whom it may Concern:

Automatic Liquid Packaging Inc., (ALP) is a Contract Manufacturer of OTC Ophthalmic Eye Care Products, located in Woodstock, Illinois. We contract manufacture for retail companies such as Rite Aid, Walgreen's, Sentry, etc.

For approximately 8 - 10 years we have been manufacturing and distributing a line of eye drops manufactured by our internal Personal Care division of ALP in 0.5 and 1.0 fluid Ounce Sizes. This line of products is in compliance as outlined in **21 CFR 349**. The line consists of the following:

<u>PRODUCT NAME</u>	<u>ACTIVE INGREDIENT</u>
Regular Eye Drops	Tetrahydrozoline HCL (a vasoconstrictor)

All the active ingredients conform to USP and are in compliance to the percents of Active Ingredients allowed in **21 CFR 349**.

Automatic Liquid Packaging, Inc., is requesting an Exemption from the labeling requirements as described in Federal Register published March 17, 1999 entitled "**Over-The-Counter Human Drugs; Labeling Requirements**" for our 0.5 and 1.0 Fluid Ounce size container box. The reason for this is that when all the Agency required labeling statements are included on the back panel in the new format and Helvetica type size, there is no room for the additional FDA labeling requirements.

Please refer to the attached copies of the carton and immediate container labeling that is included in this Application. Note the Helvetica type size and arrangement of the required statements on the Principle Display Panel. In addition, note the placement of statements such as Storage requirements, Manufactured by, Bar coding, Tamper evident, and Eye Drop Container opening instructions Statements such as this also must appear on the outside package.

98N-0337

APP4

Page 2

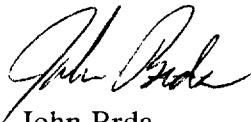
As such, Automatic Liquid packaging requests an exemption from the Helvetica Labeling letter size requirements, as described in **21 CFR 201.66** (OTC Labeling Format) for the above mentioned Ophthalmic drops for our 0.5 and 1.0 fluid ounce size.

As mentioned previously in the Request for Exemption, ALP is a Contract Manufacturer of OTC Ophthalmic Eye Drops for many Retail Distributors. If the Agency will allow the requested modifications to the Principle Display Panel as attached, we also request approval for the retail distributors we manufacture the same ophthalmic product line. These distributors are detailed in the list attached to this letter. As you could imagine, from time to time, ALP will acquire a new distributor. If the Agency allows the modified text for our in-house "Your Choice" line, as well as our current list of distributors, we respectfully request that any new distributors we add be allowed these same modifications. ALP commits that the information included on the Principle Display Panel and side panels would be identical as shown in the Attachments for all present and future distributors we manufacture this eye drop line.

Please contact me at (815) 338-9500 with any questions, or if you require any additional information.

Sincerely,

AUTOMATIC LIQUID PACKAGING, INC.



John Brda
Regulatory Affairs Manager

c Al Rothchild

.5 Oz. Tetrahydrozoline Eye Drops

Logo

**Eye
Drops**

TETRAHYDROZOLINE HCl

- Redness Reliever
Eye Drops
- Non-staining
- Clear, Colorless

.5 fl. oz. (15 mL)

Sterile

INDICATIONS: Relieves redness of the eye due to minor eye irritations.

DIRECTIONS: Instill 1 to 2 drops in the affected eye(s) up to four times daily.

FOR USE IN THE EYES ONLY.

WARNINGS: Before using with children under 6 years of age, consult your physician. Keep this and all drugs out of the reach of children. In case of accidental ingestion, seek professional assistance or contact a Poison Control Center immediately. Read warnings on box.

Active Ingredient: Tetrahydrozoline Hydrochloride 0.05%.

Inactive Ingredients: benzalkonium chloride, boric acid, EDTA, purified water, sodium borate, and sodium chloride.

KEEP CONTAINER TIGHTLY CLOSED.

TAMPER EVIDENT: IF TAMPER EVIDENT CAP IS REMOVED, DO NOT USE.

Distributed by or Manufactured by

AEOS-13-0000

1 Oz. Tetrahydrozoline Eye Drops

Logo

**Eye
Drops**

TETRAHYDROZOLINE HCl

- *Redness Reliever*
- *Eye Drops*
- *Non-staining*
- *Clear, Colorless*

Sterile

1 fl. oz. (30 mL)

INDICATIONS: Relieves redness of the eye due to minor eye irritations.
DIRECTIONS: Instill 1 to 2 drops in the affected eye(s) up to four times daily.

FOR USE IN THE EYES ONLY.

WARNINGS: Before using with children under 6 years of age, consult your physician. Keep this and all drugs out of the reach of children. In case of accidental ingestion, seek professional assistance or contact a Poison Control Center immediately. Note warnings on box.

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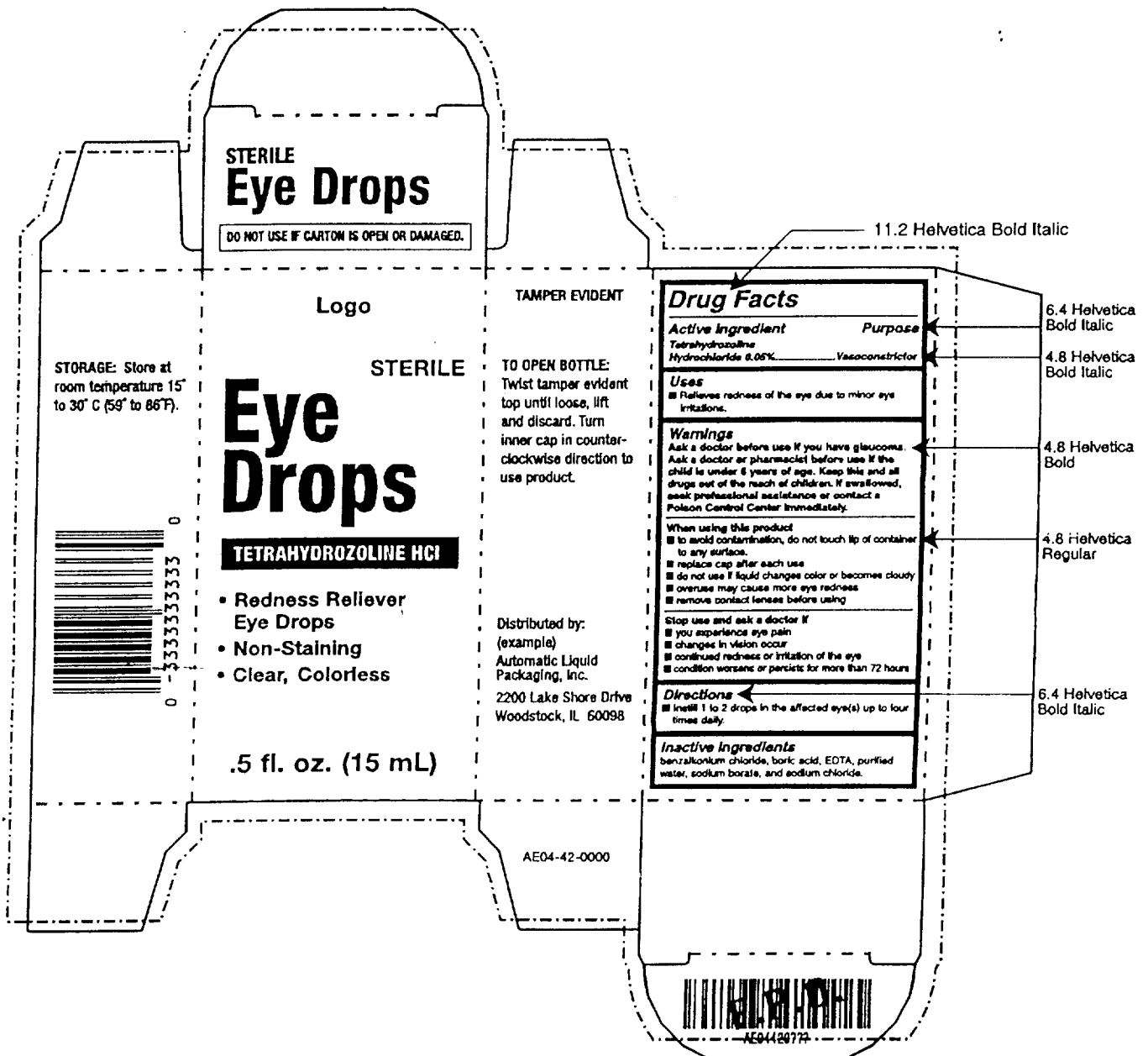
KEEP CONTAINER TIGHTLY CLOSED.

TAMPER EVIDENT: IF TAMPER EVIDENT CAP IS REMOVED, DO NOT USE.

Distributed by or Manufactured by:

AE05-13-0000

.5 Oz. Tetrahydrozoline Eye Drops



1 Oz. Tetrahydrozoline Eye Drops

STERILE
Eye Drops

DO NOT USE IF CARTON IS OPEN OR DAMAGED.

Logo

STERILE

Eye Drops

TETRAHYDROZOLINE HCl

- Redness Reliever Eye Drops
- Non-Staining
- Clear, Colorless

1 fl. oz. (30 mL)

0 - 3333333333

TO OPEN BOTTLE:
Twist tamper evident top until loose, lift and discard. Turn inner cap in counterclockwise direction to use product.

STORAGE: Store at room temperature 15° to 30°C (59° to 86°F).

AE04-42-0000

Drug Facts

Active Ingredients	Purpose
Tetrahydrozoline Hydrochloride 0.05%	Vasoconstrictor

Uses
■ Relieves redness of the eye due to minor eye irritations.

Warnings
Ask a doctor before use if you have glaucoma. Ask a doctor or pharmacist before use if the child is under 6 years of age. Keep this and all drugs out of the reach of children. If swallowed, seek professional assistance or contact a Poison Control Center immediately.

When using this product
■ to avoid contamination, do not touch tip of container to any surface.
■ replace cap after each use
■ do not use if liquid changes color or becomes cloudy
■ overuse may cause more eye redness
■ remove contact lenses before using

Stop use and ask a doctor if
■ you experience eye pain
■ changes in vision occur
■ continued redness or irritation of the eye
■ condition worsens or persists for more than 72 hours

Directions
■ Instill 1 to 2 drops in the affected eye(s) up to four times daily.

Inactive Ingredients
benzalkonium chloride, boric acid, EDTA, purified water, sodium borate and sodium chloride.

12.6 pt. Helvetica Bold

7.2 pt. Helv

5.4 pt. Helv

5.4 pt. Helv

5.4 pt. Helv

0.5 pt. Hair

2.5 pt. Bor

7.2 pt. Helv

0

+

AE04420000

.5 Oz. Tetrahydrozoline Eye Drops

Logo

Sterile

**Eye
Drops**

TETRAHYDROZOLINE HCl

- Redness Reliever
Eye Drops
- Non-staining
- Clear, Colorless

.5 fl. oz. (15 mL)

INDICATIONS: Relieves redness of the eye due to minor eye
irritations.

DIRECTIONS: Instill 1 to 2 drops in the affected eye(s) up to four
times daily.

FOR USE IN THE EYES ONLY.

WARNINGS: Before using with children under 6 years of age, consult
your physician. Keep this and all drugs out of the reach of children.
In case of accidental ingestion, seek professional assistance or
contact a Poison Control Center immediately. Note warnings on box.

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Inactive Ingredients: benzalkonium chloride, boric acid, EDTA, purified
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AE05-13-0000

1 Oz. Tetrahydrozoline Eye Drops

STERILE
Eye Drops

DO NOT USE IF CARTON IS OPEN OR DAMAGED.

Logo

STERILE

Eye Drops

TETRAHYDROZOLINE HCl

- Redness Reliever Eye Drops
- Non-Staining
- Clear, Colorless

1 fl. oz. (30 mL)

0 - 3333333333 0

TO OPEN BOTTLE:
Twist tamper evident top until loose, lift and discard. Turn inner cap in counterclockwise direction to use product.

STORAGE: Store at room temperature 15° to 30°C (59° to 86°F).

AE04-42-0000

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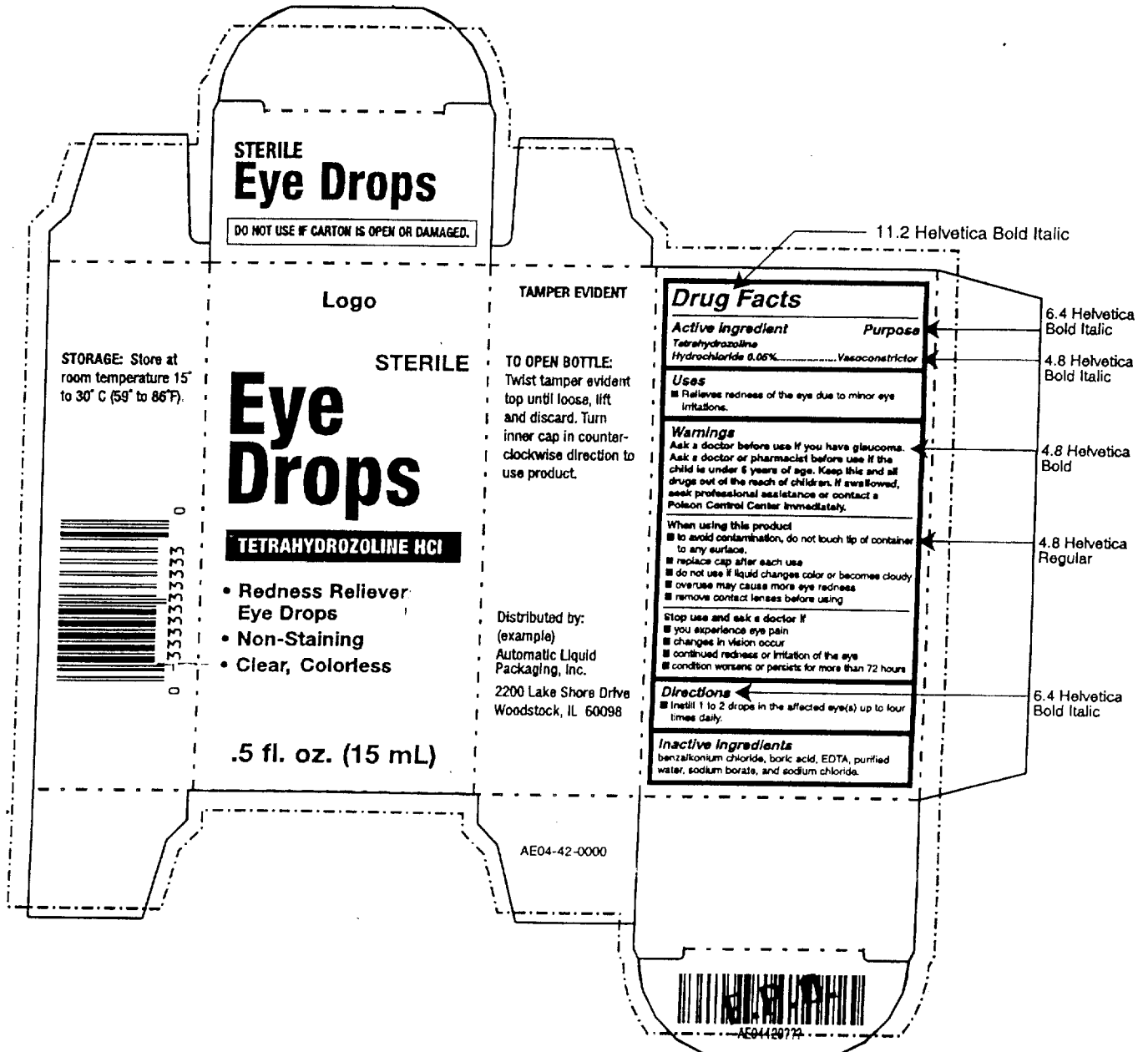
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2.5 pt. Bor

7.2 pt. Hel

AE04420000

.5 Oz. Tetrahydrozoline Eye Drops



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Logo

Sterile

**Eye
Drops**

TETRAHYDROZOLINE HCl

- Redness Reliever
Eye Drops
- Non-staining
- Clear, Colorless

.5 fl. oz. (15 mL)

INDICATIONS: Relieves redness of the eye due to minor eye irritations.

DIRECTIONS: Instill 1 to 2 drops in the affected eye(s) up to four times daily.

FOR USE IN THE EYES ONLY.

WARNINGS: Before using with children under 5 years of age, consult your physician. Keep this and all drugs out of the reach of children. In case of accidental ingestion, seek professional assistance or contact a Poison Control Center immediately. Note warnings on box.

Active Ingredient: Tetrahydrozoline Hydrochloride 0.05%.

Inactive Ingredients: benzalkonium chloride, boric acid, EDTA, purified water, sodium borate, and sodium chloride.

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INDICATIONS: Relieves redness of the eye due to minor eye irritations.

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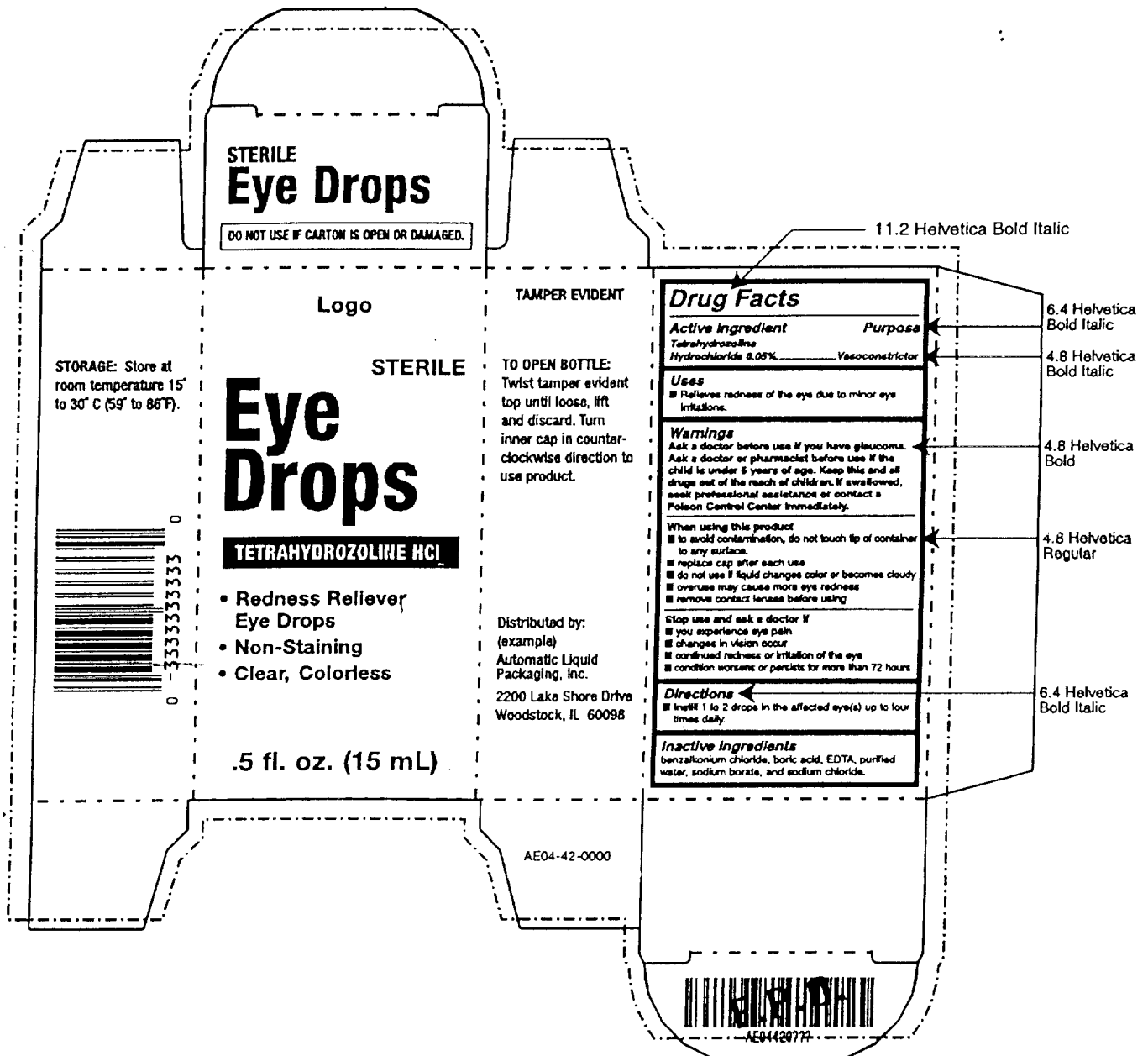
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